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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/185,318	11/03/98	REICHERT W	2978.1US

HM22/1003

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EXAMINER	
CHIN,C	
ART UNIT	**PAPER NUMBER**
1641	6

DATE MAILED: 10/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/185,318	Applicant(s) Reichert et al
	Examiner Chris Chin	Group Art Unit 1641

☒ Responsive to communication(s) filed on *Nov 3, 1998* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *25-29* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *25-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Drawings

1. The drawings are objected to for the reasons set forth in the attached PTO-948. Correction is required.

Claim Rejections - 35 U.S.C. § 112

2. Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is vague. The claim is not clear as to whether the oligonucleotide primer is the capture molecule recited in claim 25 or is used in addition to the capture molecule in claim 25 to bind the desired analyte. Also, in line 3, "biofin" should be --biotin--.

Claim 29 is vague. The recitation of "another sequence of analyte" suggests the detection of a nucleic acid analyte but claim 25 fails to recite any nucleic acid reagents for detection of a nucleic acid analyte.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 25-27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Herron et al.

Herron et al ("Fluorescent Immunosensors Using Planar Waveguides", SPIE, 1885:28-39, 1993) discloses a one-shot immunoassay which has the same level of sensitivity as current RIA and ELISA techniques but is faster and does not require separation or wash steps. The disclosed immunoassay is performed on a planar waveguide that generates an evanescent wave via total internal reflection within the waveguide (see Figure 1). In addition to the planar waveguide, the assay also employs (1) chemical modification of the waveguide to reduce non-specific binding; and (2) small, synthetic peptides for use as labeled tracer antigens. The waveguide is coated with a protein resistant material and then antibody is immobilized to the coating. The following two schemes work the best: (1) coat the underivatized silica waveguide with avidin and then couple biotinylated antigen-binding fragments (biotin-Fab') to the immobilized avidin; and (2) graft a thin layer (less than 100 Angstroms) of polymethacrylate (PMA) to the waveguide and then couple antigen-binding fragments (Fab') to the PMA layer via reactive thiol groups in the carboxy terminal region of the Fab' fragments (see page 30). Competitive (see page 30 and Figure 2) and sandwich (see page 32) immunoassay formats are disclosed.

5. Claims 25-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirschfeld et al.

Hirschfeld et al (U.S. Patent 4,558,014) discloses an assay apparatus and method employing total internal fluorescence. For use in an immunoassay, a disposable consisting of a length of precise diameter capillary tubing having an approximately axially disposed optical fiber to which is immobilized a monolayer of antibody. The disposable is also provided with an inert diluent, a preload of a known amount of tagged complement to the immobilized antibody (i.e. a fluorescent tagged antigen) and a preload of a known amount of a second fluorescent material that fluoresces at a different wavelength that does the tag. In a preferred mode of operation, the fiber is immersed in a sample of interest, and allowed to remain for a sufficient time period for both the second fluorescent material and the tagged constituent and its complement to diffuse throughout the volume between the fiber and the capillary tube wall. The total sample volume through which the fluorescent material may diffuse is defined by the geometry of the fiber and the capillary tube. Observations of both fluorescent materials are made by total reflection fluorescence, an end of the fiber being both illuminated and observed within the fiber's numerical aperture. Only that portion of the fluorescent material within the evanescent wave fluoresces, and of this, only that which tunnels back into the fiber is observed. As a result, all that is observed of either the fluorescent tag (both immobilized to the fiber and suspended in the fluid) of the second, graduating, fluorescent material is within a few hundred Angstroms of the fiber. By appropriate optical filtering, the fluorescent signals due to the tag and to the dissolved fluorescent material are

individually processed, the signal due to the tag providing a titer of the immunologically reactive species within the total volume sampled, the signal due to the second fluorescent material providing a first order measure of the concentration of the material, and hence the total volume of suspending volume (col. 3, line 42, to col. 4, line 33). The surface of the optical fiber is treated with a reagent, such as 3-aminopropyltrimethoxysilane, to provide reactive functional groups on its surface to bind to the antibodies that are to be immobilized on the optical fiber (col. 7, lines 42-68).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al or Hirschfeld et al.

See above for the teachings of Herron et al and Hirschfeld et al.

The methods of Herron et al and Hirschfeld et al differ from the instant invention in failing to teach the use of an oligonucleotide primer reagent for detection of a nucleic acid analyte as set forth in instant claim 28.

However, it would have been obvious to one of ordinary skill in the art to use an oligonucleotide primer reagent in the methods of Herron et al or Hirschfeld et al for the detection of a nucleic acid analyte because the choice of analyte dictates the reagents that are required for detection of the analyte. If the analyte that is to be detected in the methods of Herron et al or Hirschfeld et al were a nucleic acid, then one would use an oligonucleotide primer as the specific binding reagent on the waveguides used in the methods of Herron et al and Hirschfeld et al to provide for detection of the analyte nucleic acid.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-4242.

cchin
September 27, 2000

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

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Washington, D.C. 20231

DEAFACE-1094

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application
Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication should be directed to
at telephone number (703)30

Application No.: 09/185,318

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An Initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An Initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

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